

**IN THE UNITED STATES OF AMERICA  
NORTHERN DISTRICT OF TEXAS  
LUBBOCK DIVISION**

State of Texas,

*Plaintiff,*

v.

Civil Action No. 5:24-cv-00204-H

United States Department of Health and  
Human Services; Xavier Becerra, in his  
official capacity as Secretary of the United  
States Department of Health and Human  
Services; and Melanie Fontes Rainer, in her  
official capacity as Director of the Office for  
Civil Rights of the United States Department  
of Health and Human Services,

*Defendants,*

and

City of Columbus, Ohio; City of Madison,  
Wisconsin; and Doctors for America,

*Intervenor-Defendants.*

**[PROPOSED] MEMORANDUM OF LAW IN SUPPORT OF  
INTERVENOR-DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE,  
FOR SUMMARY JUDGMENT**

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The cities of Columbus, Ohio, and Madison, Wisconsin, together with Doctors for America (“Intervenor-Defendants”), having moved for leave to intervene as defendants to protect their legal interests in upholding the two regulations at issue in this case pursuant to Fed. R. Civ. P. 24, by and through their undersigned counsel, respectfully submit this memorandum of law in support of their motion to dismiss, or in the alternative for summary judgment, against the above-captioned action in its entirety pursuant to Fed. R. Civ. P. 12(b)(1) and 56(a), and adopt and join in Defendants’ arguments in support of, and motion for, dismissal and/or judgment. *See* Dkts. 19–20.

### **PRELIMINARY STATEMENT**

The confidentiality of patient health information is a cornerstone of effective health care. Congress provided critical protection for patient privacy by enacting the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) (Pub. L. 104–191, 110 Stat. 1936). In doing so, Congress expressly delegated to the Department of Health and Human Services (“HHS” or the “Department”) the authority to “promulgate final regulations” containing “standards with respect to the privacy of individually identifiable health information,” including specifically as it pertains to the “rights that an individual who is a subject of individually identifiable health information should have,” “[t]he procedures that should be established for the exercise of such rights,” and “[t]he uses and disclosures of such information that should be authorized or required.” Appx. 561 (42 U.S.C. § 1320d–2 note (codifying Pub. L. 104–191, title II, § 264)). The Department promulgated the Privacy Rules consistent with this statutory authority, considering the relevant factors and acting well within its discretion, including with respect to both Privacy Rules that Texas purports to challenge, namely, the initial, broad-gauged 2000 Privacy Rule and the 2024 Rule, which strengthen protections for information about lawful reproductive care. *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82462-01 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164) (the

“2000 Privacy Rule”); *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) (the “2024 Rule” or the “Rule”) (together, the “Privacy Rules”).

The Privacy Rules challenged in this matter are essential to the provision of health care throughout the United States. Patients and clinicians alike rely on the protections afforded by the Privacy Rules to use and disclose information regarding patient health care efficiently, effectively, and confidentially. The Privacy Rules ensure that patient information—including sensitive information touching on the patient’s symptoms, questions, fears, diagnoses, prognoses, test results, images, treatment, medical history, medication, wishes, and bills—remains confidential. When patient information does need to be disclosed—for example, when patients consult with multiple clinicians, submit bills to insurance, seek care across specialties, or even move to a new city—it is the Privacy Rules that ensure that information remains confidential. The 2024 Rule provides additional safeguards related to reproductive health care information, which is particularly sensitive and uniquely jeopardized by recent uncertainty arising from changes in law and the divergence of law between and among states. The Privacy Rules do not impede legitimate law enforcement: in fact, the Privacy Rules expressly provide exceptions to confidentiality when law enforcement has a legitimate basis to obtain confidential information and engages in the appropriate process. Intervenor-Defendants and the constituencies they represent and serve as municipalities or as clinicians are subject to and impacted by the Privacy Rules as detailed in their motion to intervene, as are all participants in the health care system who depend upon the Privacy Rules as the framework governing the transmission, maintenance, access, and disclosure of individually identifiable information regarding health care.

Texas’s request to enjoin and set aside the Privacy Rules would be devastating for patients, providers, cities, and all those who participate in the health care system. Texas disregards both the text of the HIPAA statute directing the Department to implement the rules, and the text of the Privacy

Rules as issued. It has operated pursuant to the 2000 Privacy Rule for nearly 25 years without objecting to it as invalid under the Administrative Procedure Act (“APA”), and without identifying any particular instance of injury arising from compliance with its prerequisites for disclosure to law enforcement. Texas offers no meaningful argument that the Privacy Rules violate the APA—its ostensible legal claim—but rather argues that, as a policy matter, it has decided that it would like broader access to information than the Privacy Rules permit. It asks this Court to substitute its judgment—and Texas’s policy objective—for Congress’s duly-enacted legislation and the Privacy Rules promulgated and updated at its express direction. Texas’s goal is to grant its law enforcement officials (and law enforcement officials across the country) access to records of *lawful* health care, without regard for the confidentiality of patient information or the clinician-patient relationship, without satisfying the legal prerequisites of showing a legitimate law enforcement exception, and without regard to the protections established by federal law. The Privacy Rules’ exceptions already permit reporting to law enforcement when certain limited conditions are satisfied, but Texas’s request would result in “open season” on patient records and eliminate the Privacy Rules’ protections altogether, if this Court were to accede.

Texas’s Complaint fails as a matter of law because it disregards the will of Congress as represented by the text of the governing HIPAA statute and the Privacy Rules themselves, including their explicit exceptions for law enforcement investigation, and ignores (although does not dispute) the Department’s consideration of relevant factors and the applicable legal standards. Texas cannot overcome the stark record demonstrating as a matter of law that the 2000 Privacy Rule and 2024 Rule were issued consistent with the Department’s statutory authority and that neither Privacy Rule is arbitrary and capricious.

The Complaint also fails for lack of jurisdiction because Texas brings its claims as to the 2000 Privacy Rule far too late, without even attempting to satisfy the threshold requirement of



standing. The Complaint's allegations of injury to the interests of the State of Texas are wholly conclusory and do not identify any concrete injury at all, let alone an injury sufficient to give rise to standing. Because Texas's challenge to the 2000 Privacy Rule relies on a claim of harm dating back to the 2000 Privacy Rule itself, it is decades too late, and time-barred.

For the reasons stated below and in the brief of the Department and individual Defendants (collectively, "Defendants"), this Court should dismiss Plaintiff's Complaint in its entirety, and enter judgment for the Defendants.

### **BACKGROUND**

The background regarding HIPAA and the Privacy Rules is set forth in detail in the Department's brief and is summarized here.

In 1996, Congress enacted HIPAA to "improve the efficiency and effectiveness" of health care, in part by "establish[ing] standards and requirements for the electronic transmission of certain health information." Appx. 549 (42 U.S.C. § 1320d note (codifying Pub. L. 104–191, title II, § 261)). Congress instructed HHS to adopt uniform standards "to enable health information to be exchanged electronically." 42 U.S.C. § 1320d–2(a)(1). That direction encompassed instructions to adopt uniform standards regarding the electronic exchange of health information, *id.* § 1320d–2(a), unique identifiers for participants in the health care system, *id.* § 1320d–2(b), standards for transactions and related data, *id.* § 1320d–2(a), and the security of health care information, *id.* § 1320d–2(d). Congress also expressly considered the need to adopt standards protecting the privacy of health information maintained under HIPAA and, in Section 264(a), directed HHS to submit to Congress "detailed recommendations on standards with respect to the privacy of individually identifiable health information." Appx. 561 (42 U.S.C. § 1320d–2 note). As required by HIPAA, the Department transmitted these recommendations to Congress within 12 months, on September 11, 1997. *Id.*; 42 U.S.C. § 1320d–2(a)(1); Appx. 012 (65 Fed. Reg. at 82470 (Dec. 28, 2000)).

Congress provided that if it did not enact legislation establishing these standards within 36 months after HIPAA's enactment, "the Secretary of Health and Human Services shall promulgate final regulations containing such standards." Appx. 561 (42 U.S.C. § 1320d–2 note). Further, Congress directed the Secretary to "review the standards" and "adopt modifications to the standards (including additions . . . ), as determined appropriate." 42 U.S.C. § 1320d–3(b)(1). It also included an express preemption provision, mandating that "a provision or requirement under [HIPAA], or a standard or implementation specification adopted under [HIPAA] . . . shall supersede any contrary provision of State law," with limited exceptions, including for "public health." *Id.* § 1320d–7(a)(1), (b). In its preemption provision, Congress made clear that the privacy regulations to be promulgated by HHS would constitute a floor nationwide, preempting and superseding less stringent protections but not contrary provisions of state law that may be "more stringent" than the requirements of HHS's HIPAA rules. Appx. 561–62 (42 U.S.C. § 1320d–2 note).

In 2000, after Congress did not enact legislation within the 36-month period, the Department proposed and ultimately promulgated regulations about medical privacy: the Standards for Privacy of Individually Identifiable Health Information (the 2000 Privacy Rule). 45 C.F.R. §§ 164.102–164.106, 164.500–164.535; Appx. 012 (65 Fed. Reg. at 82470 (Dec. 28, 2000)). The 2000 Privacy Rule established a set of national standards for protecting certain health information. 45 C.F.R. § 164.502; Appx. 006 (65 Fed. Reg. at 82464 (Dec. 28, 2000)). This included "general rules" for the use and disclosure of protected health information ("PHI") and rules establishing individuals' rights regarding their PHI, as well as listing specific circumstances when a covered entity is permitted to use or disclose PHI without an individual's consent. 45 C.F.R. § 164.512. The Department has continuously administered and enforced the Privacy Rule since 2000. Appx. 373 (89 Fed. Reg. at 32977 (Apr. 26, 2024)).

The Department proposed to amend the 2000 Privacy Rule to address more recent developments consistent with the principles and policy set forth by Congress in HIPAA—following an iterative rulemaking process that the statute expressly contemplated and authorized. 42 U.S.C. § 1320d–3(b)(1) (“[T]he Secretary shall review the standards adopted under section 1320d–2 of this title, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate . . . .”); *see also* Appx. 377 (89 Fed. Reg. at 32981 (Apr. 26, 2024)) (“Congress contemplated that the Department’s rulemaking authorities under HIPAA would not be static. Congress specifically built in a mechanism to adapt such regulations as technology and health care evolve . . . .”) (citing 42 U.S.C. § 1320d-3). After consulting with federal and state agencies and the National Committee on Vital and Health Statistics (“NCVHS”), and considering more than 25,900 comments, the Department promulgated the Privacy Rule To Support Reproductive Health Care Privacy (the 2024 Rule). Appx. 372, 374, 387 (89 Fed. Reg. at 32976, 32978, 32991 (Apr. 26, 2024)). The 2024 Rule’s purpose is to “amend provisions of the [2000] Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals’ ability to obtain lawful reproductive health care.” *Id.* at 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)). This rule went into effect on June 25, 2024. *Id.* at 372 (89 Fed. Reg. at 32976 (Apr. 26, 2024)).

Texas asserts that “these rules significantly harm the State of Texas’s investigative abilities because covered entities frequently cite the 2000 Privacy Rule as a reason they cannot comply with a valid investigative subpoena for documents and have already begun invoking the 2024 Privacy Rule for similar purposes.” Compl. ¶ 8; *see also* ¶¶ 85, 88. Texas does not identify any specific instance of such noncompliance at any point since either Privacy Rules’ issuance.

## PROCEDURAL HISTORY

On September 4, 2024, the State of Texas brought suit against the Department, the Department's Secretary Xavier Becerra, and the Department's Director of the Office for Civil Rights Melanie Fontes Rainer (Defendants) alleging two counts under the Administrative Procedure Act: that, by promulgating the 2000 Privacy Rule and 2024 Rule, Defendants purportedly exceeded their statutory jurisdiction or authority per 5 U.S.C. § 706(2)(A) (Count I), and acted in a manner that was arbitrary and capricious per 5 U.S.C. § 706(2)(C) (Count II). On November 18, 2024, the Court entered the parties' agreed-upon briefing schedule and requested dispositive motions on or before January 17, 2025. *See* Dkt. 15. On January 15, 2025, Texas requested an extension to the briefing schedule for dispositive motions, which the Court granted that same day, ordering dispositive motions due on or before February 7, 2025. *See* Dkts. 17–18. On January 17, 2025, Intervenor–Defendants filed their Motion to Intervene, seeking to protect their interests and to be heard regarding the sweeping relief that the State seeks, including by moving for summary judgment and dismissal as to both counts of the Complaint under Fed. R. Civ. P. 12(b)(1) and 56(a).

## ARGUMENT

Summary judgment should be granted when “there is no genuine dispute as to any material fact” and the moving party “is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). It is the movant's burden to demonstrate “the absence of a genuine issue of material fact,” and entry of summary judgment is required against any party “who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.” *Jones v. United States*, 936 F.3d 318, 321 (5th Cir. 2019) (quoting *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994)). A court may grant summary judgment if it determines that plaintiffs lack “standing to pursue their claims.” *Paxton v. Dettelbach*, 105 F.4th 708, 711 (5th Cir. 2024).

A motion to dismiss for lack of subject matter jurisdiction should be granted if a plaintiff lacks the standing required for the Court to adjudicate the claims. Fed. R. Civ. P. 12(b)(1); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (holding that standing is jurisdictional; absent standing, the court lacks subject matter jurisdiction to adjudicate the claims and must dismiss). In assessing the allegations on a motion to dismiss, the Court must accept the complaint’s well-pled, factual allegations as true, *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981), but not its conclusory allegations or legal conclusions, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). “‘The party invoking federal jurisdiction bears the burden of establishing’ standing” throughout the case, “and, at the summary judgment stage, such a party ‘can no longer rest on . . . ‘mere allegations,’ but must ‘set forth’ by affidavit or other evidence ‘specific facts.’”” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 411–12 (2013) (quoting *Lujan*, 504 U.S. at 561).

A motion to dismiss for lack of jurisdiction should be granted when the claims are time-barred. Plaintiff bears the burden of establishing the timeliness of each claim alleged; untimely claims must be dismissed. *See Austral Oil Co. v. Nat’l Park Serv.*, 982 F. Supp. 1238, 1246 (N.D. Tex. 1997) (“Plaintiffs must show” APA claim timely “within six years prior to filing suit.”). “[F]ailure to sue . . . within the limitations period” under the APA “is not merely a waivable defense. It operates to deprive federal courts of jurisdiction.” *Am. Stewards of Liberty v. Dep’t of Interior*, 960 F.3d 223, 229 (5th Cir. 2020).

**I. THE APA CLAIMS FAIL BECAUSE THE DEPARTMENT ACTED WITHIN ITS AUTHORITY AND WITH DUE CONSIDERATION OF THE RELEVANT FACTORS, AND THE RULES ARE NOT ARBITRARY AND CAPRICIOUS.**

As Defendants establish in their opening brief, Congress expressly delegated rulemaking authority to the Department under HIPAA, and the Privacy Rules are squarely within the scope of that delegated statutory authority and valid under the APA. *See* 5 U.S.C. § 706(2)(A). Under the APA, an agency’s action must be upheld, unless it is “arbitrary, capricious, an abuse of discretion,

or otherwise not in accordance with law” or is in excess of statutory authority. *Id.* § 706(2)(A), (C). In reviewing a claim under the APA, the Court is to presume the agency’s action is valid and is to consider only whether that action “was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). The Court’s review is “neither sweeping nor intrusive.” *Fort Bend Cnty v. U.S. Army Corps of Eng’rs*, 59 F.4th 180, 194 (5th Cir. 2023). The Court may not “substitute [its] judgment for that of the agency.” *Overton Park*, 401 U.S. at 416 (quoting *Amin v. Mayorkas*, 24 F.4th 383, 393 (5th Cir. 2022)); *see also Barr v. Sec. & Exch. Comm’n*, 114 F.4th 441, 447 (5th Cir. 2024) (“Agency decisions are ‘presumptively valid; the petitioner bears the burden of showing otherwise.’”) (quoting *Tex. Tech Physicians Assocs. v. U.S. Dep’t of Health & Hum. Servs.*, 917 F.3d 837, 844 (5th Cir. 2019)) (cleaned up). When Congress statutorily grants an agency the authority and discretion to propose and enact rules, the agency’s discretion is notably broad. *Little Sisters of the Poor v. Pennsylvania*, 591 U.S. 657, 676–77 (2020) (agency has broad discretion to craft guidelines when granted on the face of the statutory text).

**A. The APA Claims Fail as to the 2000 Privacy Rule.**

HHS acted within its delegated statutory authority in promulgating the 2000 Privacy Rule, and appropriately exercised its discretion, as the APA requires. The 2000 Privacy Rule took the relevant factors into account and addressed precisely the issues Congress directed the Department to address, namely: “(1) The rights that an individual who is a subject of individually identifiable health information should have. (2) The procedures that should be established for the exercise of such rights. (3) The uses and disclosures of such information that should be authorized or required.” Appx. 561 (42 U.S.C. § 1320d–2 note).

*First*, the Department addressed the rights of an individual who is a subject of individually identifiable health information. *See id.*; 45 C.F.R. §§ 164.524(a)(1), 164.526(a)(1), 164.528(a)(1);

Appx. 005 (65 Fed. Reg. at 82463 (Dec. 28, 2000)). The Privacy Rule granted “individual[s] . . . a right of access to inspect and obtain a copy of protected health information in designated record set,” 45 C.F.R. § 164.524(a)(1), a “right to have a covered entity amend protected health information or a record about the individual,” *id.* § 164.526(a)(1), and “a right to receive an accounting of disclosures of protected health information,” *id.* § 164.528(a)(1). The Department recognized that privacy of personal information—and particularly, of personal medical information—is a vital individual interest and essential to the effective provisions of health care. Appx. 006, 009 (65 Fed. Reg. at 82464, 82467 (Dec. 28, 2000)). It found that medical privacy is necessary for individual patients and clinicians alike, and for the functioning of the health care system as a whole; effective care cannot be provided unless individuals are willing and able to share their most intimate details, and that willingness depends on an expectation of privacy and confidential treatment. *Id.* at 009–010 (65 Fed. Reg. at 82467–68 (Dec. 28, 2000)). It concluded that individuals have an interest in avoiding the disclosure of such personal matters, including “matters vital to the care of their health.” *Whalen v. Roe*, 429 U.S. 589, 600 (1977); *see also* Appx. 005 (65 Fed. Reg. at 82464 (Dec. 28, 2000)).

**Second**, the Department addressed the procedures required to protect those rights. *See* 45 C.F.R. §§ 164.506(b)–(c), 164.508–10; Appx. 561 (42 U.S.C. § 1320d–2 note). The Privacy Rule details the process for patients to access and request amendment to their own protected health information, 45 C.F.R. §§ 164.524; 164.526, and vests them with the right to direct disclosure of their records to another doctor, *id.* § 164.506(b)(1) (“A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.”). The 2000 Privacy Rule also confers a right to file a complaint against a “covered entity [for] not complying” with the rule and to have that complaint investigated. *Id.* § 160.306(a). Critically, the Department recognized that the advancement of technology and shift to electronic record-keeping and communications “have reduced or eliminated many of the financial

and logistical obstacles that previously served to protect the confidentiality of health information and the privacy interests of individuals,” Appx. 007 (65 Fed. Reg. at 82465 (Dec. 28, 2000)), and concluded that “protection of privacy must be built into the routine operations of our health care system.” *Id.* at 009 (65 Fed. Reg. at 82467 (Dec. 28, 2000)).

**Third**, and of particular relevance to Texas’s purported interest, the Department addressed “[t]he uses and disclosures of such information that should be authorized or required.” Appx. 561 (42 U.S.C. § 1320d–2 note); *see* 45 C.F.R. § 164.512. The 2000 Privacy Rule sets out detailed standards regarding the use and disclosure of PHI; *see, e.g.*, 45 C.F.R. §§ 164.502, 164.512, which is defined as “individually identifiable health information” that is “transmitted” or “maintained” in “electronic media” or “any other form or medium,” *id.* § 160.103. The 2000 Privacy Rule provides that PHI is protected from use or disclosure without an individual’s authorization, ***except in certain circumstances***, also specified in the 2000 Privacy Rule. *Id.* § 164.502(a). Those exceptions include exceptions for law enforcement and other state interests: PHI can be used and disclosed without written patient authorization for purposes including treatment, payment, and health care operations, *id.* § 164.502(a)(1)(ii), and may be disclosed to law enforcement officials pursuant to a court order, subpoena, or administrative request, and in any judicial or administrative proceeding in response to an order of the court or tribunal, *id.* § 164.512(e)–(f).

There is no dispute, and no allegation to the contrary, that the Department considered the relevant factors—including the rights that individuals who are the subject of individually identifiable health information should have, the procedures for the exercise of such rights, and the uses or disclosures of such information that should be authorized or required—and engaged in thorough consultation with federal and state agencies, and an extensive public comment process, before promulgating the final 2000 Privacy Rule. *See* Compl. ¶¶ 24–35 (making no allegations regarding the rulemaking process); Appx. 005–007, 009–010, 012 (65 Fed. Reg. at 82463–65, 82467–68,



82470, 82474 (Dec. 28, 2000)) (considering factors Congress detailed, noting delay caused in part by approximately 17,000 comments received, and engaging in required consultations); 45 C.F.R. § 164.502 (detailing general rules for uses and disclosures of PHI); Appx. 561 (42 U.S.C. § 1320d–2 note) (requiring the Secretary’s recommendations to address specific considerations).

The undisputed record of rulemaking, consistent with statutory authority, considering and addressing the relevant factors, also establishes that the Department did not engage in action that was “arbitrary, capricious, [or] an abuse of discretion” when promulgating the 2000 Privacy Rule. 5 U.S.C. § 706(2)(A); *see Barr*, 114 F. 4th at 447 (“Agency decisions are presumptively valid; the petitioner bears the burden of showing otherwise.”) (cleaned up); *Huawei Techs. USA, Inc. v. Fed. Comm’n Comm’n*, 2 F.4th 421, 434 (5th Cir. 2021) (“Our role is to determine whether the agency’s decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.”) (cleaned up); *Associated Builders & Contractors of Texas, Inc. v. Nat’l Lab. Rels. Bd.*, 826 F.3d 215, 224–25 (5th Cir. 2016) (“To affirm an agency’s action, we need only find a rational explanation for how the [agency] reached its decision.”).

For these reasons, and those set forth by Defendants in their motions to dismiss and/or for summary judgment on January 17, 2025, Texas’s claims regarding the 2000 Privacy Rule fail as a matter of law and should be dismissed in their entirety.

#### **B. The APA Claims Fail as to the 2024 Rule.**

Summary judgment is also warranted with respect to claims seeking to enjoin and set aside the 2024 Rule. While more recent, the Department’s issuance of the 2024 Rule falls just as squarely within its authority and discretion.

That the 2024 Rule was promulgated more recently is not a reason to set it aside, as Texas seems to suggest. HIPAA expressly authorizes the Secretary to “review” and “adopt modifications to the standard . . . as deemed appropriate.” 42 U.S.C. § 1320–3(b)(1). Pursuant to this grant of

authority, the Department issued the 2024 Rule consistent with HIPAA’s purpose “to improve the efficiency and effectiveness of the health care system, which includes ensuring that individuals have trust in the health care system.” Appx. 385 (89 Fed. Reg. at 32989 (Apr. 26, 2024)). More specifically, the 2024 Rule “directly advances the purposes of HIPAA by setting minimum protections for PHI . . . thereby improving the effectiveness of the health care system by ensuring that persons are not deterred from seeking, obtaining, providing, or facilitating reproductive health care.” *Id.* at 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)).

Texas maintains that the Department lacks the authority to promulgate new rules limiting how regulated entities share information with state governments and seeks to set those rules aside in favor of allowing broad access by the State to reproductive health care information, in particular. That Texas disagrees with the policy enacted by Congress in HIPAA and followed by the Department in enacting the 2024 Rule is not a sufficient legal basis to strike it down under the APA.

The Department’s authority and appropriate exercise of discretion are yet again clear on the record. In enacting HIPAA, Congress made clear that, in the promulgation of privacy regulations, HHS should balance the rights of individuals against certain public interests: HIPAA states that it should not be understood to invalidate or limit “reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” 42 U.S.C. § 1320d–7(b). In accordance with that provision, the Department issued rules that make clear that covered entities may disclose an individual’s PHI, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. *See* 45 C.F.R. § 164.512(b)(1).

The 2024 Rule follows HIPAA’s directive. It does not prohibit disclosures of PHI where the request is to lawfully investigate a matter of public health, consistent with 42 U.S.C. § 1320d–7(b), *see* Appx. 388–90, 394 (89 Fed. Reg. at 32992–94, 98 ((Apr. 26, 2024))), and maintains the existing

provisions permitting use and disclosure for public health oversight activities. 45 C.F.R. § 164.512(b), (c). But because the Department defined “public health” to encompass “population-level activities to prevent disease and promote health of populations,” Appx. 396 (89 Fed. Reg. at 33000 (Apr. 26, 2024)), as opposed to the kind of investigations of individuals for “the mere act of seeking, obtaining, providing, or facilitating health care,” *id.* at 398 (89 Fed. Reg. at 33002 (Apr. 26, 2024)), the permitted disclosure is more narrow than Texas would like. The 2024 Rule also does not prohibit disclosure in connection with the **unlawful** provision of reproductive health care, 45 C.F.R. § 164.502(a)(5)(iii)(B), again consistent with Congress’s directive—but more narrow than Texas’s preferred policy.

The 2024 Rule’s definitions are clear, and the Rule is well within the ambit of the Department’s discretion and authority, including for all of the reasons Defendants argue.

As with the 2000 Rule, on this undisputed record, Texas cannot show that the Department engaged in action beyond its authority or that was “arbitrary, capricious, [or] an abuse of discretion” when promulgating the 2024 Rule. 5 U.S.C. § 706(2)(A), (C); *see Barr*, 114 F.4th at 447 (“Agency decisions are presumptively valid; the petitioner bears the burden of showing otherwise.”) (cleaned up); *Huawei Techs.*, 2 F.4th at 434 (“Our role is to determine whether the agency’s decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.”) (cleaned up); *Associated Builders & Contractors of Texas, Inc.*, 826 F.3d at 224–25 (“To affirm an agency’s action, we need only find a rational explanation for how the [agency] reached its decision.”). Texas cannot satisfy its burden with respect to the 2024 Rule, and its claims should be dismissed in their entirety and judgment entered for Defendants as to that Rule too.

**C. The Privacy Rules Do Not Improperly Infringe on State Law Enforcement Authority.**

Moreover, for all of the reasons stated by the Defendants, the Privacy Rules do not improperly infringe on state law enforcement authority; the exceptions provided by the Privacy Rules regarding law enforcement and judicial administrative proceedings are consistent with the Department's legal authority, reflect its reasoned judgment and consideration of the relevant factors, and are legally valid. *See* Dkt. 20 at 15-27. Texas's claims have no merit on this ground either.

**II. THE COMPLAINT FAILS AT THE THRESHOLD BECAUSE THE INJURY ALLEGED IS INSUFFICIENT TO SUPPORT STANDING, AS WELL AS TIME-BARRED.**

The Court should not reach the merits of Texas's claims because Texas lacks standing and its claims as to the 2000 Privacy Rule are untimely. As a result, the Court lacks subject matter jurisdiction, for all of the reasons Defendants argue.

To meet the "irreducible constitutional minimum of standing," *Lujan*, 504 U.S. at 560, a plaintiff must demonstrate: (1) "injury in fact," (2) "that is fairly traceable to the challenged conduct of the *defendant*," and (3) "likely to be redressed by a favorable judicial decision," *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (emphasis added). "[S]tanding is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press" and "for each form of relief that they seek." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021). The burden to plead those facts and establish its standing rests on plaintiff. *See Clapper*, 568 U.S. at 411–12. Standing is jurisdictional; absent standing, the Court cannot adjudicate the claims and must dismiss. *See Lujan*, 504 U.S. at 559–61.

Plaintiffs also bear the burden of establishing the timeliness of their claims under the APA. 28 U.S.C. § 2401(a); *Corner Post, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 603 U.S. 799, 800 (2024). The general statute of limitations for civil suits against the government applies to APA challenges when, as here, Congress has not enacted another statute of limitations for a specific type

of challenge. *Corner Post, Inc.*, 603 U.S. at 808. That limit provides that complaints are barred unless “filed within six years after the right of action first accrues.” 28 U.S.C. § 2401(a); *Corner Post, Inc.*, 603 U.S. at 800 (quoting *Bay Area Laundry and Dry Cleaning Pension Tr. Fund v. Ferbar Corp. of Ca.*, 522 U.S. 192, 201 (1997)). A claim accrues when it is “complete and present,” at which point a litigant can sue. *Corner Post, Inc.*, 603 U.S. at 800.

**A. Texas Has Failed to Establish Standing.**

The generalized objections that Texas asserts are inadequate to establish its standing to sue on these claims. Texas does not plead any facts identifying any injury to its interests as a result of either the 2000 Privacy Rule or the 2024 Rule. Instead, it relies on generalized and conclusory allegations that “these rules significantly harm the State of Texas’s investigative abilities,” Compl. ¶ 8, without specifying a single instance in which such harm has occurred. Although Texas complains that “the 2000 Privacy Rule harms” it “because covered entities in receipt of an administrative subpoena will frequently cite the rule as the reason they cannot comply,” *id.* ¶ 85, and “[i]n at least one instance a covered entity has cited the 2024 Privacy Rule as a reason it cannot comply” with Texas’s subpoena, *id.* ¶ 88, it does so in wholly conclusory fashion and without factual allegations that the recipients in fact refused to provide information or that the purported investigation was affected by these responses. Texas completely ignores that the Privacy Rules expressly allow disclosure of PHI even without patient authorization for clearly defined, legitimate law enforcement purposes, including rules that specifically permit disclosures when reporting “child abuse or neglect,” reporting “abuse, neglect, or domestic violence” to the extent “required by law,” and responding to legally authorized information demands, such as warrants and subpoenas. 45 C.F.R. §§ 164.512(b), (c), (e), (f); *see also* Appx. 391 (89 Fed. Reg. at 32995 (Apr. 26, 2024)) (“The Privacy Rule always has and continues to permit disclosure of PHI to support public policy goals, including disclosures to support criminal, civil, and administrative law enforcement activities . . .”). Texas provides no

specific facts, nor has it detailed specific crimes it is investigating, to support a conclusion that these exceptions are inadequate or in any way injurious to the state's interest.

In light of its failure to plead the type of concrete injury-in-fact necessary to establish standing under binding precedent, including *Lujan*, as Defendants demonstrate, Texas has failed to carry its burden on this threshold jurisdictional issue and its claims must be dismissed. 504 U.S. at 560–61, 563–67; *Ctr. for Biological Diversity v. U.S. Env't Prot. Agency*, 937 F.3d 533, 545 (5th Cir. 2019) (“Article III demands more than . . . conclusory assertions.”).

**B. If Texas's Injury Is Adequate to Establish Standing, Any Claim Related to the 2000 Privacy Rule Is Necessarily Time-Barred.**

Because the only injury Texas even attempts to allege is a generalized injury arising from the promulgation of the 2000 Privacy Rule, Compl. ¶ 8, its claims are time-barred. Even if such allegations were sufficiently concrete to confer standing—and they plainly are not—they would arise only from the 2000 Privacy Rule itself and not from any subsequently occurring injury. Even under *Corner Post*, 603 U.S. at 809, the APA's six-year limit expired long ago. For that reason, too, the claims regarding the 2000 Privacy Rule, which Texas has been subject to for over two decades, fail as a matter of law and should be dismissed as untimely.

**CONCLUSION**

For the foregoing reasons and those set forth by Defendants in support of their motion to dismiss or in the alternative for summary judgment, *see* Dkt. 20, and the administrative record cited therein, the Court should dismiss the Complaint in its entirety pursuant to Fed. R. Civ. P. 12(b)(1) and/or enter judgment for Defendants and dismiss as to the entirety of the Complaint pursuant to Fed. R. Civ. P. 56(a).

Date: January 17, 2025

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on January 17, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

/s/ Jennifer R. Ecklund  
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